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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,746

07/08/2005

Masaki Baba

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EXAMINER

PEPITONE, MICHAEL F

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1796

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,746	Applicant(s) BABA ET AL.
	Examiner Michael Pepitone	Art Unit 1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/8/05, 6/30/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recites the limitation "the silicone compound (C) and the N-substituted acrylamide (D) in the mixed solution" in the last two lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, and 9-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Baba *et al.* (WO 01/171415). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claims 1-2, and 18: Baba *et al.* teaches an ocular lens material {contact lens [instant claim 18]} (1:5-12) comprising a compound having an ethylenically unsaturated group

and a polydimethylsiloxane through a urethane bond (2:60-4:45; 7:30-67), and a pyrrolidone derivative in which a polymerizable group is a methylene group [instant claim 1] (4:18; 9:58-63), wherein the pyrrolidone derivative is present in an amount of 7.5-40% [instant claim2] (10:24-56; Tables 1 and 3 {col. 27-28}).

Regarding claim 9: Baba *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1], wherein the repeating number of polydimethylsiloxane is 28 (7:28-45, compound A-1).

Regarding claim 10: Baba *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1]. The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents. Therefore, the claimed effects and physical properties, i.e. a tensile modulus of 0.2 to 0.8 MPa, and a stress relaxation under loading a fixed load for 30 seconds is 8 to 15%, would inherently be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Regarding claims 11-12: Baba *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1], wherein the water content is 29-50% by weight (Tables 4 and 6 {col. 29 and 30}).

Regarding claims 13-14: Baba *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1], further comprising tris(trimethylsiloxy)silylpropyl methacrylate (8:27-9:1).

Regarding claims 15-16: Baba *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1], further comprising N,N-dimethylacrylamide (10:11-18).

Regarding claim 17: Baba *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1], further comprising at least one crosslinking agent (4:25-32).

Claims 19, 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Baba *et al.* (WO 01/171415). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claim 19: Baba *et al.* teaches a method for preparing ocular lens material (1:5-12) comprising mixing a compound having an ethylenically unsaturated group and a polydimethylsiloxane through a urethane bond (2:60-4:45; 7:30-67), and a pyrrolidone derivative in which a polymerizable group is a methylene group (4:18; 9:58-63), and a photopolymerization initiator (20:63-21:16) or thermal polymerization initiator (19:47-20:8); the mixture was introduced to a mold; thermal or photo cured (22:40-23:25); a surface treatment procedure was employed to impart hydrophilic properties and lipid stain resistance (22:10-16); the residual monomers were extracted from the lens (25:17-45); the ocular lens material was hydrated (22:55-57).

Regarding claim 21: Baba *et al.* teaches the basic claimed method [as set forth above with respect to claim 19], further comprising a crosslinking agent (12:1-34; Tables 1 and 3 {col. 27-28}).

Regarding claim 22: Baba *et al.* teaches the basic claimed method [as set forth above with respect to claim 19], further comprising polymerizable UV absorbents and polymerizable dyes (16:66-17:3; 19:22-36).

Regarding claims 23-24: Baba *et al.* teaches the basic claimed method [as set forth above with respect to claim 19], further comprising 0.5 to 100 parts of a diluent {based on 100 parts monomer mixture}, specifically acetone (21:17-38).

Regarding claims 25-26: Baba *et al.* teaches the basic claimed method [as set forth above with respect to claim 19], wherein the surface treatment procedure was a plasma treatment [instant claim 25] (22:10-16), and a plasma treatment with oxygen [instant claim 26] (22:10-16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-8 rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) as applied to claim 1 above, and further in view of Shibata *et al.* (US 4,547,543). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claims 3-8: Baba *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1]. Baba *et al.* does not teach 1-methyl-3-methylene-2-pyrrolidone as the pyrrolidone derivative. However, Shibata *et al.* teaches a contact lens composition comprising 1-methyl-3-methylene-2-pyrrolidone [instant claims 3-4] (1:1-5; 1:54-62, 2:1-14). Baba *et al.* and Shibata *et al.* are combinable because they are concerned with a similar technical difficulty, namely the preparation of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 1-methyl-3-methylene-2-pyrrolidone, as taught by Shibata *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Shibata *et al.* suggests that such pyrrolidones provide good polymerizability with (meth)acryloyl groups, thereby decreasing poor optical and mechanical properties resulting from phase separation (1:40-62), and is an equivalent alternative means of providing a contact lens comprising pyrrolidone derivatives.

At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 1-methyl-5-methylene-2-pyrrolidone [instant claims 5-6], and 5-methyl-3-methylene-2-pyrrolidone [instant claims 7-8], which are regioisomers of 1-methyl-3-methylene-

2-pyrrolidone. A prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979) [see MPEP 2144.09].

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) as applied to claims 19 and 26 above, and further in view of Valiant, JR. *et al.* (US 2002/0102415). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claim 27: Baba *et al.* teaches the basic claimed method [as set forth above with respect to claims 19 and 26]. Baba *et al.* does not teach a plasma treatment with a mixture of oxygen and water [instant claim 27]. However, Valiant, JR. *et al.* teaches a method for surface treating contact lens material comprising a plasma treatment with a mixture of oxygen and water {air drawn through 5% hydrogen peroxide solution} [instant claim 27] (§ 10, 58). Baba *et al.* and Valiant, JR. *et al.* are combinable because they are concerned with a similar technical difficulty, namely plasma treatment of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined plasma treatments in the presence of oxygen and water, as taught by Valiant, JR. *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Valiant, JR. *et al.* suggests that such strong oxidizing plasma promote adhesion for bonding of the subsequent carbon deposition

layer (§ 58), and is an equivalent alternative means of providing a plasma treatment for contact lenses.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) as applied to claims 19 and 26 above, and further in view of Hayashi *et al.* (US 6,503,632). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claim 28: Baba *et al.* teaches the basic claimed method [as set forth above with respect to claims 19 and 26]. Baba *et al.* does not teach a plasma treatment with a mixture of oxygen and tetrafluoromethane [instant claim 27]. However, Hayashi *et al.* teaches a method for surface treating contact lens material comprising a plasma treatment with a mixture of oxygen and tetrafluoromethane [instant claim 27] (1:10-18; 21:7-15). Baba *et al.* and Hayashi *et al.* are combinable because they are concerned with a similar technical difficulty, namely plasma treatment of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined plasma treatments in the presence of oxygen and tetrafluoromethane, as taught by Hayashi *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Hayashi *et al.* suggests that such plasma treatment provide a substrate with substituents which a chemical reaction can proceed {the surface of the molded article may be chemically bonded further with a polymer or monomer} (21:16-23), and is an equivalent alternative means of providing a plasma treatment for contact lenses.

Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) as applied to claims 19 and 26 above, and further in view of Walther *et al.* (US

6,379,004). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claims 29-30: Baba *et al.* teaches the basic claimed method [as set forth above with respect to claims 19 and 26]. Baba *et al.* does not teach a plasma treatment with a mixture of oxygen and organic silane [instant claim 29], specifically tetramethoxysilane [instant claim 30]. However, Walther *et al.* teaches a method for surface treating ophthalmic lens material comprising a plasma treatment with a mixture of oxygen and tetramethoxysilane [instant claims 29-30] (1:4-6; 10:48-62). Baba *et al.* and Walther *et al.* are combinable because they are concerned with a similar technical difficulty, namely plasma treatment of ophthalmic lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined plasma treatments in the presence of oxygen and tetramethoxysilane, as taught by Walther *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Walther *et al.* suggests that such plasma treatment provide a substrate with both an interface layer and a grease protection layer (10:48-50), and is an equivalent alternative means of providing a plasma treatment for ophthalmic lenses.

Claims 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) as applied to claims 19 and 26 above, and further in view of Turek *et al.* (US 2002/0137811). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claims 31-35: Baba *et al.* teaches the basic claimed method [as set forth above with respect to claims 19 and 26]. Baba *et al.* does not teach a plasma treatment with a mixture

of oxygen and methane [instant claim 31], and a mixture of oxygen, nitrogen, and methane [instant claim 32]. Baba *et al.* does not teach a surface treatment that is a coating method of a hydrophilic polymer coating [instant claim 33], specifically plasma polymerization of hydrophilic monomers [instant claim 34], and plasma-induced graft polymerizations [instant claim 35]. However, Turek *et al.* teaches a method for surface treating ophthalmic lens material comprising a plasma treatment with a mixture of oxygen and methane [instant claim 31], and a mixture of air {oxygen and nitrogen} and methane [instant claim 32] (§105-110). Turek *et al.* also teaches a method for surface treating ophthalmic lens material comprising a plasma treatment coating method of a hydrophilic polymer coating [instant claim 33], specifically plasma polymerization of hydrophilic monomers [instant claim 34], and plasma-induced graft polymerizations [instant claim 35] (§105-110). Baba *et al.* and Turek *et al.* are combinable because they are concerned with a similar technical difficulty, namely the surface treating of ophthalmic lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined plasma treatments in the presence of air and methane, and plasma induced polymerizations, as taught by Turek *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Turek *et al.* suggests that such plasma treatments provide a surface which is more ophthalmically compatible (§ 106), and is an equivalent alternative means of providing a surface treatment for ophthalmic lenses.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) as applied to claim 19 above, and further in view of Niwa *et al.* (US 5,516,467). For

the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claim 36: Baba *et al.* teaches the basic claimed method [as set forth above with respect to claims 19]. Baba *et al.* does not teach a method of coloring the ocular lens material by using a vat dye [instant claim 36]. However, Niwa *et al.* teaches a method for coloring contact lenses by using a vat dye [instant claim 36] (1:4-8; 2:26-49). Baba *et al.* and Niwa *et al.* are combinable because they are concerned with a similar technical difficulty, namely the coloring of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined vat dyes, as taught by Niwa *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Niwa *et al.* suggests that such vat dyes can be uniformly dispersed in the monomer mixture (2:64-3:10; 3:30-40), and is an equivalent alternative means of providing a method for coloring contact lenses.

The prior art made of record and not relied upon is considered pertinent to applicants' disclosure. See attached form PTO-892.

Correspondence

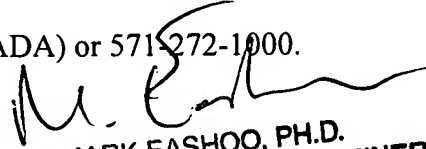
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pepitone whose telephone number is 571-270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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SUPERVISORY PATENT EXAMINER

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